EXHIBIT 1

2008 Folio 877

IN THE HIGH COURT OF JUSTICE

QUEEN'S BENCH DIVISION

COMMERCIAL COURT

B E T W E E N :-

(1) PORTON CAPITAL TECHNOLOGY FUNDS (A BODY CORPORATE)

(2) PORTON CAPITAL INC.

(3) PLOUGHSHARE INNOVATIONS LIMITED

Claimants

-and-

(1) 3M UK HOLDINGS LIMITED

(2) 3M COMPANY

Defendants

Re-AMENDED PARTICULARS OF CLAIM

A. INTRODUCTION

1. At all material times Acolyte Biomedica Limited ("Acolyte") was a limited company registered and carrying on business in the United Kingdom. In particular its business was in the development, production and marketing of various products whose purpose was to detect and/or test for certain micro-organisms, especially the detection of methicillin resistant *Staphylococcus aureus* ("MRSA") on clinical nasal swab samples. *Staphylococcus aureus* ("*S. aureus*") is a practically ubiquitous type of bacteria, whilst MRSA refers to strains of *S. aureus* that have developed extensive resistance to antibiotics. *S. aureus* is not normally considered a major health threat, but MRSA and related organisms are colloquially known as "~~super-bugs~~superbugs" and are a major concern within the health sector including in hospitals worldwide.

2. At all material times until completion of the sale and purchase agreement referred to below, Acolyte's entire issued share capital was owned by various shareholders including the Claimants, as set out in Schedule 1 to the

~~SPA~~said sale and purchase agreement. The shareholders of Acolyte are collectively referred to in this document as "the Vendors". The ~~First and Second~~ Claimants were between them owners of the issued shares in Acolyte indicated in column 2 of SPA Schedule 1, and as indicated in columns 3 and 4 of said Schedule were to receive ~~47.59~~58.14% of the initial consideration and ~~43.48~~60.4% of the additional consideration consisting of the Earn Out Payment to be paid in 2010.

3. At all material times the Second Defendant ~~3M Company ("3M")~~ was a Delaware Corporation which was the holding and/or principal company in a multi-national group (**"the 3M Group"**) whose headquarters were in St. Paul in Minnesota, USA. The 3M Group carried on business worldwide and in a number of different fields of activity and in particular had a global medical division which sought to sell certain medical products into the health sector worldwide. References in this statement of case to "3M" include, unless the context otherwise indicates, to the Second Defendant, 3M's Medical Division and to companies in the 3M Group (including the First Defendant).

4. At all material times the First Defendant was a subsidiary of the Second Defendant~~3M~~ and was incorporated in the United Kingdom.

5. By an agreement in writing dated 14 February 2007 ("the SPA") the Vendors agreed to sell to the First Defendant the shares in Acolyte on the terms and conditions set out therein. In particular the SPA provided as follows.

> *"2.1 Upon and subject to terms of this Agreement, each Vendor hereby agrees to sell and Purchaser agrees to purchase the shares set out opposite that Vendor's name in column (2) of Schedule 1 of this Agreement free from all Encumbrances ...*
>
> *3.1 The Consideration ... is the aggregate of :*
>
> *(a) £10,400,000 in cash (the "Initial Consideration"); and*
>
> *(b) Any payments to be made pursuant to clause 4 (Earn- Out Payments) ...*
>
> ***4. EARN-OUT PAYMENTS***
>
> *4.1 As further consideration for the purchase of the Shares hereunder, the Purchaser shall pay to the Vendors an amount equal to (i) 100% of the Earn-Out Product Net Sales up to a maximum amount of £41,000,000, less (ii) the total amount of all Employee Incentive Payments. ...*

4.2 *For the purposes of clause 4.1: "Net Sales" means the net sales amount ... for the fiscal year ended December 31, 2009 ... with respect solely to Earnout Products ..."*

4.14 *The Purchaser undertakes to the Vendors that in the period from the date of this Agreement to December 31, 2009 (the "Earn Out Period") that:*

(a) the Earn Out Products are actively marketed (a) in the United States, the European Union, Canada, and Australia (the "Major Markets") and (b) those countries where 3M has obtained regulatory approval to do so;

(b) (to the extent required) regulatory approval is diligently sought for the Earn Out Products in the Major Markets;

(c) the business selling the Earn Out Products is supported by resources from the following functional areas within the Purchaser's Group: Marketing, Communications, Information Technology, Technical Service, Legal, Tax and Accounting to a similar overall degree as such resources are made available to other businesses within 3M's Medical Division;

(d) the sales representatives for the Earnout Product will be compensated for the sale of the Earnout Product in the same general manner as sales representatives in 3M's Medical Division are compensated for the sale of other 3M products;

(e) as soon as reasonably practical after Completion, training module would be developed for sales representatives selling the Earnout Products which will be commensurate in standing with the training modules for sales representatives of other products sold by the 3M's Medical Division;

(f) marketing and other training and customer support materials will be prepared to support the sales of the Earnout Products, will be kept reasonably current and will be of an overall standard and quality similar to those used to support the sale of other products within the 3M infection prevention business unit;

(g) the Earn Out Products will be sold as "3M" branded products.

4.15 *Except as expressly set forth in Clause 4.14, the Vendors acknowledge that the Purchaser is under no obligation or duty to conduct its business in a manner that increases the amount payable under this Clause 4. Each Vendor hereby acknowledges and agrees that the Earn-Out Payment is contingent on the Company's future performance and is not guaranteed."*

6. The Earn Out Products as referred to in clause 4 of the SPA were defined in Schedule 7 thereof and included BacLite MRSA ("BacLite") and various other products.

6A By the provisions of clauses 4.14(a) to (g) inclusive, as set out above, it was intended and agreed by the Vendors and the First Defendant that the acts contemplated thereby would be performed by 3M, i.e. not only by the First Defendant but where necessary or otherwise appropriate by the companies within the 3M Group as a whole (or third parties contracted by them). In the premises, by clauses 4.14(a) to (g), the First Defendant undertook that each of the acts required by clauses 4.14(a) to (g) would be carried out by 3M (or by third parties contracted by 3M).

6B In relation to BacLite, the obligation in clause 4.14(a) actively to market BacLite required (taken together with clause 4.15 and the other obligations of clause 4.14) that 3M:

(1) would (subject to obtaining any necessary regulatory approval in the jurisdiction in question) market BacLite in a manner so as to increase the sales of BacLite and the sales revenue derived therefrom in the period to 31 December 2009 (and so increase the amounts payable under clause 4.1); and/or

(2) would market BacLite with the care and skill to be expected of a competent company which was experienced in the worldwide marketing of healthcare products including infection prevention products generally and MRSA detection products specifically and whose aim was to increase the sales of BacLite and the sales revenue derived therefrom in the period to 31 December 2009 (and so increase the amounts payable under clause 4.1); and/or

(3) in order to increase the sales of BacLite and the sales revenue derived therefrom in the period to 31 December 2009, would devote a similar amount of resource, expenditure, effort and expertise and would accord priority to the marketing of BacLite as to the marketing of the products within 3M's Medical Division, including MRSA detection products and other infection prevention products, irrespective of the respective returns to 3M in relation to such other products; and/or

(4) would not stop or lessen its marketing activities prior to 31 December 2009 because of any reduction in the current or forecast profitability to 3M of the product, or because of any shortfall in actual sales against forecasts or of any downwards revision/s in forecasts of actual sales or sales revenues in the period prior to 31 December 2009.

6C In relation to BacLite, the obligation "diligently" to seek regulatory approval was an obligation to seek relevant approvals ~~(not including in respect of the European Union, where approval had already been obtained)~~ with the care, skill and speed to be expected of an experienced and competent entity specialising in the development of infection prevention (including MRSA detection) products, and which was committed to increasing the sales of BacLite and the worldwide sales revenues from BacLite in the period to 31 December 2009 irrespective of the current or forecast profitability to 3M of the product.

6D Further, each of the obligations in clauses 4.14(c) to (f), each being specific obligations serving the overall obligations in clauses 4.14(a) and (b) diligently to seek regulatory approvals for, and actively to market the Earn-Out Products was required to be performed in a manner that increased the amounts payable to the Vendors (having regard to clause 4.15) irrespective of the current or forecast profitability to 3M of the product.

B. OVERVIEW

7. BacLite is a product developed and sold by Acolyte in the European Union before Acolyte's sale to ~~3M~~ the First Defendant to test for the presence of MRSA in clinical nasal (or groin) swab specimens or samples. BacLite performs in 5 hours assays of swab samples collected nasally in clinical settings to produce a positive or negative result for the presence of MRSA.

8. ~~Despite the First Defendant's its acquisition of Acolyte, 3M sought from the outset to exploit MRSA diagnostic products other than BacLite. 3M introduced its BacLite sales force to competing MRSA testing products as more sensitive substitutes for BacLite~~. As explained below in detail in paragraphs 19 to 29A, 3M launched US ~~trials~~ clinical ~~trials~~studies for BacLite in a manner which was not diligent and which ~~is inexplicable on any reasonable basis, that appeared designed or destined to result~~resulted in

failure and/or poor trials results; ~~by inappropriately comparing BacLite results for the presence of MRSA to bacteria culture results for the presence of any type of *S. aureus* and that calls into question either its competence or its intent. When BacLite correctly tested positive for MRSA less frequently than the control tested positive for any type of *S. aureus*, 3M treated BacLite as insufficiently sensitive and halted the trials~~

(1) 3M used a different comparator to BacLite than had been used in its successful UK regulatory trials. The comparator used in the US clinical studies, MSA, was inappropriate, alternatively, could only appropriately be used for clinical studies after proper verification of the proposed methodology in pre-clinical trials and after making any necessary changes to such methodology (and, if required, to the BacLite assay) in order to optimise its sensitivity and selectivity.

(2) 3M failed properly to train those conducting the US clinical studies (or the pre-clinical evaluations and pre-clinical studies in the US prior to such studies) and failed properly to monitor such studies and evaluations.

(3) Despite a report co-authored by eleven 3M technical staff which recommended that future trials could be undertaken with better results using a proper comparator that they predicted US regulators would approve, 3M deemed BacLite unreliable and decided not to re-run its US clinical studies using the comparator used in the UK trials, MSAOx, ~~to abort its marketing and development. Pending disclosure and/or the provision of further information, the Claimants do not at present make a positive case as to 3M's motivation or intent but, at this stage, the Claimant contends that the manner of the launch of the clinical trials leads to a possible inference that the reason for this was that 3M was not fully committed to the success of the trials.~~

(4) ~~9. 3M's decision to deem BacLite scientifically unreliable and commercially unsound only months after the acquisition was unjustified. 3M chose to ignore~~ 3M did not "actively" market BacLite within the meaning of the Agreement in the Major Markets and in those other territories for which regulatory approval had been

obtained in that: it failed to employ sales people and technical support staff who were suitably qualified or experienced; did not adopt suitable sales methods; did not produce BacLite kits in sufficient numbers to satisfy the demand for customer evaluations. As a result, despite positive technical results in the large majority of its customer trials it ~~and~~ failed to convert them into sales, despite 3M's own market data identifying high market interest in BacLite in major markets especially the US and other markets.

(5) 3M did not diligently seek regulatory approval in certain territories besides the US as a result of the failure of the US clinical studies and further as a result of a shortage of BacLite kits necessary to conduct such trials.

10. Further 3M ignored or did not pay sufficient regard to peer-reviewed scientific publications showing that BacLite ~~is superior~~ has significant advantages compared to more commercially lucrative ~~gene sequencing~~DNA sequence-based detection technology in detecting newly emerging strains of MRSA.

11. For example, it has been shown by Malhotra-Kumar et al. in the September 2008 issue of *Journal of Clinical Microbiology* (~~pages 46~~ (3181-3182) that "the BacLite assay cleanly sidesteps the problems faced by DNA sequence-based detection methods due to the tremendous sequence variations observed in the *SCCmec* cassette (2), resulting in impressive sensitivity that should withstand the constant emergence of novel *SCCmec* variants. In conclusion, the new 3M BacLite assay is a promising assay that combines the advantages of culture with the rapidity of molecular method-based detection." There the authors retracted an earlier comment that BacLite might not detect certain MRSA strains by noting that changes made in the assay in February 2007 (before the sale of Acolyte) resolves that issue, and further reported that they had "also validated the new BacLite assay" with respect to 52 well-characterized strains of MRSA.

12. Likewise von Eiff, Maas et al., Journal of Antimicrobial Chemotherapy (2008) 61, 1277-1280, reported in March 2008 a study whose aim was to assess the reliability of the BacLite assay "to successfully detect MRSA strains circulating currently in Germany and other parts of Europe on the basis of several well-characterized *S. aureus* strain collections" (1277). They reported that "[m]ore

than 700 methicillin-susceptible and methicillin-resistant strains covering >90% of all registered European MRSA *spa* types within the SegNet network were studied" using BacLite. They found that "[a]ll 513 MRSA strains tested were recognized as methicillin-resistant" and "[n]one of the 211 methicillin-susceptible strains were detected as positive" (1277).

13. The scientific literature therefore confirms that BacLite is ~~actually~~similar in sensitivity and specificity whilst being a more ~~sensitive and~~ cost-effective method ~~of MRSA detection~~ than other MRSA diagnostic technology, such as ~~gene sequencing~~DNA sequence-based detection technology~~, which would need~~. Further, the latter would require a costly process of continual refinement to keep up with newly emerging strains ~~by constant production of a wide array of costly new assays by 3M Group~~.

14. 3M failed actively to market BacLite in the Major Markets and in those territories for which regulatory approval was obtained as pleaded in paragraphs 35 to 43 below, and failed to support the business of selling BacLite with resources to the same overall degree as other businesses within 3M's Medical Division as pleaded in paragraphs 43 to 45 below. ~~As pleaded in paragraph 8 above, T~~the Claimants will contend that ~~the First Defendant's and 3M's decisions in regards to BacLite are consistent with the inference that 3M was not fully committed to BacLite, notwithstanding the obligations a decision to undermine BacLite and breach its undertakings in the SPA, and, further, that 3M instead were committed to support and market a competitor product from 3M it called Fastman, despite the reduction in hospital MRSA morbidity and mortality and public health expenditures that BacLite's cost-effective widespread use would entail, particularly in regards to newly emerging strains of MRSA~~.

15. ~~Having previously concealed from Vendors its true position on BacLite, the~~The First Defendant, through 3M repudiated the SPA on or before 15 August 2008 by reasons of the breaches of it referred to below and/or by informing Vendors that the BacLite business had only generated US$1.07 million in total Earn Out payment as of that date, and that Vendors would not be paid even that sum unless they consented by 28 August 2008 to the immediate cessation of the Earn Out business, whilst advising further that the First Defendant would take all steps to cease the Earn Out business without

Vendors' consent after such date, thereby evincing an intention not to be bound by the SPA.

C. ~~OTHER~~ SPECIFIC BREACHES OF THE SPA

16. ~~In breach~~The First Defendant breached ~~in particular of~~ clauses 4.14 of the SPA and in particular ~~in breach of~~ sub-paragraphs (a) and/or (b) and/or (c) and/or (e) and/or (f) in that 3M ~~the Defendant~~ failed actively to market the Earn Out products and/or seek regulatory approval therefor diligently and/or at all, and failed to carry out the other related obligations specified in sub-clauses (c), (e) and (f) and, the First Defendant ~~in~~ breached ~~of~~ clauses 4.14 and 4.15, in that 3M did not take the steps contemplated ~~did not perform all of its undertakings~~ in clause 4.14 in a manner that would increase the Earn Out payment due to Claimants as agreed in clause 4.15.

17. Particulars of these breaches are set out below under the following broad but in some instances overlapping headings.

(1) Regulatory approval

(2) Failure to market BacLite actively

(3) Failure to support the business of selling Earn Out Products

~~(4) Inadequate training that undermined BacLite from the outset~~

~~(5) Marketing and other training and customer support materials~~

18. The particulars provided below are based on ~~(a)~~ the Claimants' own knowledge of BacLite as re-amended following review of the Defendants' disclosure to date ~~and (b) the limited amount of 3M's documentation to which they have to date had access. The Claimants reserve the right to supplement these particulars after discovery and/or the provision of Further Information~~.

Regulatory Approval

19. Acolyte secured regulatory clearance for BacLite in the European Union before the sale of Acolyte through UK trials that measured among other factors the sensitivity and ~~selectivity~~specificity of the product when used with clinical specimens. Sensitivity is measured in terms of avoiding false negatives (i.e. where BacLite indicates that there is no MRSA when the

control/comparator sample indicates the presence of MRSA) and ~~selectivity~~ specificity is measured in terms of avoiding false positives (i.e. where the product purports to show MRSA when the comparator does not).

20. BacLite showed high sensitivity in the UK trials by testing positive for MRSA 94.6% of the time when the same clinical nasal swab samples tested positive for MRSA in the comparator in the UK trials. BacLite also showed high specificity in the UK trials by testing negative for MRSA 96.9% of the time when the same clinical nasal swab samples tested negative for MRSA in the comparator.

21. The US ~~trials~~ clinical study which ~~were begun~~was initiated in September 2007 after ~~3M's~~ the First Defendant's acquisition of Acolyte ~~were~~was not conducted in an appropriate manner but on the contrary ~~were~~was conducted in a manner which was inappropriate, and lacked diligence ~~incomprehensible in some respects, and showed a complete absence of diligence~~. Specifically and as set out below, and as evidenced in part by the content of 3M's own "BacLite Technical Report":

(1) An inappropriate comparator was used;

(1A) Even after 3M became aware that an inappropriate comparator had been used, the clinical study was not re-launched using an appropriate comparator;

(1B) No proper pre-clinical evaluations or pre-clinical studies were carried out; and

(2) ~~Tests were~~The ~~trials~~ clinical study was not diligently designed, supervised and monitored as required by protocol.

Comparator

22. In the UK trials undertaken prior to completion of the SPA the comparator used was MSAOx with 7.5% NaCl and 4 µg/ml of oxa~~y~~cillin. MSA stands for Mannitol-Salt Agar and "Ox" stands for oxa~~y~~cillin which is an antibiotic. ~~Mannitol is a nutrient favoured by many types of bacteria.~~ A 7.5% concentration of table salt (NaCl) in ~~mannitol tends to favour~~Mannitol Salt Agar favours the growth of staphylococci, such as *S. aureus* which is more tolerant of salt than other bacteria. Mannitol is a nutrient that can be utilised

by *S.aureus* which as a result, appear as characteristic yellow colonies with a yellow halo. Other species of staphylococci, such as the coagulase-negative staphylococci (CoNS) whilst able to grow on MSA cannot utilize manitol and therefore do not appear as yellow colonies. A 4 µg/ml concentration of oxaycillin antibiotic in ~~mannitol salt agar~~Mannitol Salt Agar inhibits the growth of staphylococcus, such as *S. aureus* ~~generally~~, except for the strains that are resistant to antibiotic (i.e. MRSA). MSAOx therefore is a growth medium that selects ~~and tests~~ for and reveals the presence of MRSA in samples. MRSA grows on MSAOx as characteristic yellow colonies with a yellow halo, which is a positive screening result. Testing clinical nasal swab samples in BacLite assays and in MSAOx, whilst comparing the results, is a scientifically sound, accepted and successful method of testing BacLite for sensitivity and ~~selectivity~~specificity.

23. For the US clinical study ~~trials~~ [redacted] However, the comparator in fact used was not MSAOx, but rather MSA on its own without oxaycillin. As it lacks antibiotic, MSA is not selective for the isolation of MRSA, ~~grows all kinds of *S. aureus* without selecting for MRSA~~. When clinical nasal swabs are tested in BacLite assays and in MSA, a comparison of the two (without the further step of a confirmatory test to indicate whether MRSA is present) will necessarily be misleading and/or meaningless, since the presence of any *S. aureus* in the sample may result in a positive result in MSA while the BacLite assay selects for MRSA. ~~The misleading comparison predictably makes BacLite appear insensitive but only because it is a comparison of MRSA positive results with positive results for the presence of any kind of *S. aureus* including non-resistant strains~~. 3M used a cefoxitin disk diffusion test as a confirmatory test to indicate whether yellow colonies growing on the comparator, MSA, were MRSA or methicillin sensitive *Staphylococcus aureus* ("MSSA"). The US clinical study therefore tested the BacLite assay for sensitivity to and specificity for MRSA by comparing, respectively, its negative and positive results with the results found in the same clinical sample using MSA and the cefoxitin disk diffusion confirmatory test.

23A. 3M did not diligently seek US regulatory approval in that MSA is an inappropriate comparator and is not made appropriate by the use of a cefoxitin disk diffusion confirmatory test:

(1) MSA is not a selective medium for the isolation of MRSA. At the material times, reasonably competent practice in obtaining regulatory approval for MRSA diagnostic products was to use a selective medium as a comparator such as MSAOx or a chromogenic agar plate containing the antibiotic cefoxitin.

(2) In particular, in early 2007, the use of a selective medium had been adopted with FDA approval in the US clinical studies of another MRSA detection product, "Xpert MRSA", in which a chromogenic agar plate containing cefoxitin had been used as a comparator. Claims for the sensitivity and specificity of "Xpert MRSA" were permitted to be made based on a comparison with the results obtained using selective media. In the premises, if 3M had acted diligently and sought to use MSAOx (or other selective media) in the US clinical study, the FDA would have permitted such use and would have permitted 3M to make sensitivity and selectivity claims for BacLite in the US on the basis of such trials.

(3) Trials of MRSA detection products using selective media as a comparator are less prone to error than trials using MSA. This is because using MSA as a comparator potentially increases both the number of colonies per plate to be tested and the number of non-MRSA colonies to be tested, and such increase in the colonies to be tested increases the risk of error in the confirmatory test:

a. Because the selective medium, MSAOx, only supports the growth of colonies of MRSA and methicillin-resistant CoNS bacteria, and not MSSA, fewer colonies will grow on a MSAOx plate than on a MSA plate. Therefore when colonies are initially grown on a selective medium fewer colonies per plate require testing for MRSA using the cefoxitin disk diffusion confirmatory test.

b. The cefoxitin disk diffusion test is inherently subjective since the test for the presence of MRSA is dependent on whether the diameter of

the circular zone of growth inhibition of the test culture around a 30 ug cefoxitin disc is ≤21mm, which is indicative of MRSA, or ≥22mm which is indicative of MSSA. Where the diameter is close to the threshold diameter value, there is an element of judgment whether the cultured colony is MRSA, MSSA or one of the intermediate forms of *S. aureus* with partial antibiotic resistance, borderline oxacillin resistant *Staphylococcus aureus* (known as "BORSA").

c. The size of the said diameter is dependent on a number of variables besides the kind of bacterial colony, including the manufacturer and lot number of the cefoxitin disks used, the temperature and time of incubation of the cefoxitin disc diffusion plates, and the use of appropriate MRSA and MSSA control cultures. Such factors increase the risk that where diameters are observed close to the threshold value, colonies of MSSA or BORSA will be wrongly identified as MRSA or *vice versa*.

d. The risk of errors in correctly judging the outcome of the confirmatory test increases with the number of colonies from a given plate to be tested since there is greater risk of error in the subjective determination of whether the diameter of the zone of inhibition is ≤21mm to indicate the presence of MRSA.

e. Further, the risk of erroneously identifying as MRSA colonies of non-MRSA bacteria increases with the number of non-MRSA colonies tested.

(4) A further problem with the use of MSA as a comparator is that it may result in the cefoxitin disk diffusion confirmatory test wrongly identifying "damaged MRSA" as normal MRSA:

a. Damaged MRSA can arise in patients enrolled in a clinical study who have been recently treated with antibiotics or where nasal swabs have been stored at 4°C for long periods of time. It is preferable that damaged MRSA should not be detected as positive by an MRSA test. BacLite is unlikely to detect damaged MRSA as they will be inhibited by the cefoxitin present during the first BacLite incubation.

b. Damaged MRSA is unlikely to grow on MSAOx due to the presence of the antibiotic. However, unlike MSAOx or other selective media, damaged MRSA may recover and grow on MSA. Colonies of MRSA grown from damaged MRSA will subsequently be identified as MRSA in the cefoxitin disk diffusion confirmatory test, even though the BacLite test on the same swab is negative.

c. As a result, the use of MSA as a comparator, and the consequent risk that damaged MRSA will grow on that medium, increases the risk that BacLite will wrongly appear to be giving false negatives, and therefore appear to have lower sensitivity than is in fact the case.

(5) Further or alternatively, given a choice between using MSA and MSAOx, since MSAOx had already been used successfully in BacLite's UK trials, MSAOx was the only appropriate choice of comparator, even if MSA would otherwise have been appropriate.

23B. In the alternative, if MSA was appropriate for use as a comparator with a cefoxitin confirmatory test, it could not appropriately be used in the US clinical study without first conducting a closely monitored verification with such comparator using the methodology proposed to be used for the US clinical study, and, in the event that lower sensitivity or specificity was found in such trials, without first making such adjustments as were necessary to the proposed US clinical study methodology (and, if required, to the BacLite assay) in order to optimise such sensitivity and specificity.

24. ~~MSA was a wholly inappropriate comparator whose use was contrary to industry norms and standards, and is inexplicable in a trial attempting to demonstrate high sensitivity. The use of MSA as the comparator in the US clinical trials predictably led to a very much lower sensitivity for BacLite, in the region of 50-55%, and hence much lower than that which would be expected (about 95%) on the basis of the UK trials.~~

~~25.~~ [redacted]

[redacted]

26. [redacted]

Lack of Diligent Supervision and Monitoring of US Trials Pre-Clinical Evaluation and Pre-Clinical Studies

26A 3M failed diligently to seek regulatory approval in the United States because it failed to carry out appropriate pre-clinical evaluations and pre-clinical studies of BacLite in the United States. In particular:

(1) A reasonably competent company in the position of 3M would, well in advance of the US clinical study, have (a) through the use of appropriate pre-clinical evaluations verified that BacLite worked in the United States as it had already been found to work in Europe in the UK regulatory trials, and (b) through the use of appropriate pre-clinical studies tested BacLite under the conditions of the US clinical study.

(2) Such evaluations and studies should have involved an initial pre-clinical evaluation of BacLite in 3M's US laboratory carried out by experienced Acolyte personnel using the proposed clinical study protocol and appropriate strains and samples followed by a pre-clinical study of BacLite in the laboratory of one or more US hospitals.

(3) Such evaluations and studies should have been undertaken whether or not the comparator to be used in the US clinical study was to differ from that in the UK trials, but were of particular importance if a different comparator was intended to be used.

(4) Further, such evaluation and studies were important given other differences between the UK trials and the US clinical study. As well as the difference in the comparator used, the US clinical study was to use only clinical swab samples taken from patients and not to include spiked swab samples, were to take place in numerous different locations (i.e. in various locations in the United States), be carried out by different people, and could involve detection of potentially different strains or combinations of strains of MRSA (since strains of MRSA may differ from region to region).

(5) The purpose of such evaluations and studies would be to ensure that the methodology proposed to be adopted in the US clinical study would produce the expected results for sensitivity and specificity, i.e. results similar to those obtained in the UK trials. In the event that similar results were not obtained, the evaluations and studies would enable errors in the methodology to be identified or errors in performing the method to be identified and would enable any necessary adjustments to be made to the methodology for the proposed US clinical study to avoid such errors from occurring in the clinical study.

(6) In order to fulfil such purposes, a diligent pre-clinical study at a US hospital laboratory was required to:

a. use the same comparator as the proposed US clinical study;

b. follow, so far as practicable, the same methodology as proposed for the US clinical study;

c. be conducted by laboratory technicians who were sufficiently skilled and had been appropriately trained to conduct the evaluation;

d. be closely monitored by 3M;

e. be performance evaluated by 3M after its conclusion, including by rapid investigation at 3M's laboratories of any false negative or false positive results to determine their cause;

f. be conducted sufficiently far in advance of the full US clinical study that any changes necessary to the US clinical study methodology and/or to the BacLite assay could be made before the US clinical study commenced.

(7) 3M conducted pre-clinical studies of BacLite in the United States, prior to the US clinical study, at Marshfield in around July and/or August 2007. However, these studies did not fulfil the above requirements in that:

a. The Marshfield pre-clinical study did not take place far enough in advance of the start of the US clinical study for its results effectively to be used in optimising the US clinical study

b. The Marshfield pre-clinical study used MSAOx as a comparator, rather than MSA with a cefoxitin confirmatory test as 3M had decided to use in the US clinical study.

c. The Marshfield pre-clinical study was not closely monitored by 3M. In particular, weekly data sets including discarded data were not obtained or properly analysed by 3M. The two most experienced individuals regarding BacLite, Mr. O'Hara and Mr. Robinson, had great difficulty in obtaining information relating to the Marshfield evaluation and accordingly were not able to assess the lessons to be learned from the Marshfield evaluation for the purposes of the forthcoming US clinical study.

d. The Marshfield pre-clinical study used the wrong strain of *S.aureus* as its positive control.

e. 3M failed to ensure that sufficient reagents necessary properly to conduct the Marshfield pre-clinical study were made available.

f. The Marshfield pre-clinical study failed adequately to screen the study population from whom swabs were taken, including with regard to the likelihood of the presence of damaged MRSA.

g. Further, it is to be inferred from the numerous errors during the Marshfield pre-clinical study that those performing such studies were insufficiently trained and/or insufficiently supervised by 3M

h. In any event, no performance analysis of the Marshfield pre-clinical study was conducted before the US clinical study began.

26B. In acting as aforesaid, 3M assumed, or appeared to assume, that the sensitivity and specificity BacLite achieved in the UK trials would be achieved in the US clinical study without providing sufficient training to the US clinical study sites and monitoring adherence to the clinical study protocol at these sites, or any further refinement or development of the methodology for such trials or of BacLite itself. Such assumption, if made, did not reflect a diligent approach to the obtaining of US regulatory approval.

Lack of Diligent Design, Supervision and Monitoring of the US Clinical Study

26C. 3M's US clinical study was planned to be conducted at nine sites but had only commenced at seven sites before it was suspended. The laboratory staff at the study sites had not used BacLite before and, in some cases, had previously been unfamiliar with the comparator method, i.e. the use of MSA with a cefoxitin confirmatory test. 3M failed to train the laboratory staff adequately to conduct the clinical study. 3M failed adequately to monitor or supervise the clinical study. In particular, the Claimants will rely on the fact that 3M was heavily reliant on Mr. Robinson to conduct such training, and Mr. Robinson was, at the time, overstretched and unable to commit the time required for adequate training. The lack of adequate training, supervision or monitoring is also to be inferred from the many mistakes made by those conducting the US clinical study, and the consequently large amount of discarded data from the study.

27. 3M failed diligently to monitor BacLite's US clinical study ~~trials~~ to ensure adherence to protocol, particularly the requirement that the internal temperature of the incubator be maintained at 37°C. 3M neglected to ensure that all personnel monitoring the US clinical study ~~trials~~ were aware that incubator temperature is a critical variable when performing BacLite assays.

28. During the US clinical study ~~trials~~ the relevant incubators were on occasions either improperly set or the temperatures were otherwise not properly or diligently maintained or monitored, such that at one study site the incubator temperature averaged only 33 degrees C, whilst at another site there was no

temperature data recorded ~~they fell to 35°C or rose to 39°C~~ and this had an adverse effect on ~~BacLite trial~~the US clinical study results.

29. [redacted]

29A. 3M failed diligently to design and monitor the US clinical study in other respects. If the US clinical study had been diligently designed, including after making necessary adjustments to the clinical study protocol that would have been made following a proper pre clinical evaluation and pre-clinical study, then the following steps, which were not taken, would have been taken:

(1) More detailed directions and training would have been given, and the study would have been better monitored to ensure that the correct temperature was maintained, for example: by specifying the use of repeater pipettes to speed up the manual handling steps in the BacLite assay and thereby reduce the risk of decreases in temperature to unacceptably low levels during such manual handling steps; by specifying that both lids should be kept closed when running the BacLite processor; and by specifying that incubation temperatures should always be recorded.

(2) 3M would have ensured that the reagents to be used in the US clinical study were of the correct specification. In particular:

a. 3M would have ensured that lysostaphin, the reagent used for cell lysis in BacLite, which was in turn necessary for BacLite to detect MRSA, had sufficiently high activity after freeze drying. As a result, low cell lysis in the US clinical study caused by low levels of lysostaphin activity would have been avoided.

b. 3M would have ensured that the BacLite broth had the correct pH (7.4 +/- 0.2) so as to allow adequate cell lysis by the lysostaphin. As a result, low cell lysis caused by a broth pH of around 6.8 would have been avoided.

(3) 3M would have designed the US clinical study so as to increase the reliability of the results as to BacLite's sensitivity by increasing the

number of MRSA positive swabs used. 3M would have done so by removing from the study population swab samples taken from any patient who had been treated with antibiotics within the previous week, since nasal swabs from such patients are less likely to contain MRSA.

(4) 3M would also have limited the risk that swabs containing damaged MRSA would be used in the US clinical study by, as above, excluding from the population those who had used Vicks Sinex (or similar substances) or antibiotics in the previous week, since if nasal swabs from such patients still contain MRSA then they are more likely to be damaged MRSA.

(5) At the least, 3M would have ensured that swabs taken from those who had used Vicks Sinex (or similar substances) or antibiotics in the previous week were correctly identified so that in the event of poor results in the clinical study, the potential causes of such results could be properly analysed.

(6) 3M would have ensured that variations across the different study sites sites were minimised, including by specifying that distilled water be provided to all test sites from the same source; that the same brand and lot number of cefoxitin disk be used (since the amount of cefoxitin in each disk can vary from manufacturer to manufacturer and from lot to lot) and by specifying the manner in which control MSSA and MRSA cultures were to be prepared and used so that a comparison of BacLite performance between different test sites could properly be made.

(7) 3M would have run the clinical study at a fewer number of sites, particularly having regard to the limited resources 3M had made available to train or monitor those performing the clinical study. Had it done so 3M would have been better able to ensure that the study was performed correctly, with accordingly higher recorded sensitivity and specificity for MRSA.

Failure to re-run the US clinical study ~~***Other Factors***~~

29B. [redacted]

29C. Despite, in December 2007 and early 2008, initially contemplating re-running the US clinical study, 3M failed to do so. In so failing, 3M did not diligently pursue regulatory approval in the United States. In particular:

(1) In a properly designed and controlled clinical study in the United States, the BacLite assay would, or would likely, detect MRSA in clinical swab samples with high sensitivity and specificity.

(2) The adverse US clinical study results were not attributable to any flaws in the BacLite assay but to 3M's failures as aforesaid diligently to prepare for, design and implement such study.

(3) In particular, a re-run US clinical study using MSAOx as a comparator would, or would likely, result in much higher observed sensitivity and specificity. By early 2008 at the latest, 3M itself recognised that the use of MSA had led to misidentification of isolates as MRSA using the cefoxitin disk diffusion method, that MSAOx was an internationally recognised and more appropriate comparator than MSA, had decided to use MSAOx in further clinical studies, and had sought and obtained the FDA's approval to the use of such comparator in future clinical studies. In the circumstances, it was not diligent to fail to re-run the US clinical studies using MSAOx.

(4) Further, by early 2008, 3M had itself recognised numerous other errors in the way in which the US clinical studies had been performed, including many of those pleaded in paragraphs 21 and 23 to 29A above. In the circumstances, in failing to re-run the US clinical studies with appropriate temperature control andimproved protocols, directions and monitoring to prevent such errors from being repeated, 3M's approach lacked diligence.

29D. If the US clinical study had been re-run appropriately, as pleaded above, it would, or would likely, have shown comparable sensitivity and specificity as

observed in the UK trials. Following such approval, BacLite could have been actively marketed in the United States. In the premises, in deciding not to re-run the US clinical study, 3M did not diligently seek regulatory approval.

30. ~~The~~Further, 3M lacked diligence in deciding not to re-run the US clinical study in that, [redacted]

31. [redacted]

32. Despite its own experimental results showing high sensitivity for BacLite using 24 hour old clinical nasal swabs, 3M has internally cited the spiked swab results to create a misleading rationale to abandon BacLite in breach of the SPA. In the premises, in failing to re-run the US clinical study in partial reliance on the observed sensitivity for spiked swabs that had been stored for 24 hours, 3M did not act diligently.

32A. Further or in the further alternative, if and insofar as the rationale for 3M's decision not to re-run the US clinical study related to the allegedly poor commercial prospects for BacLite such decision was a failure diligently to pursue regulatory approval in that BacLite had strong commercial prospects if actively marketed, as further pleaded in paragraphs 36C to 40, below.

Immediate Impact of 3M's Handling of US Clinical ~~Trials~~Study

32B. If 3M had prepared for, designed and performed the US clinical study diligently, then the US clinical study would, or would likely, have shown BacLite to have a similar sensitivity and specificity as had been shown by the UK regulatory trials. Alternatively, even if the US clinical study had not been successful and had had to be re-run, the results obtained from a diligently designed, performed and evaluated re-run clinical study taking due consideration of lessons learned from the original US clinical study would, or would likely, have been successful. In the premises, if 3M had diligently sought regulatory approval in the United States, such approval would, or would likely, have been obtained by the end of 2007, alternatively by the middle of 2008.

32C. In the further alternative, by reason of 3M's failure diligently to seek regulatory approval in the United States, the chance (which was substantial) that the US clinical study would have been successful was lost.

33. ~~The halt of~~By 10 October 2007 at the latest 3M had already significantly scaled back its marketing investment and related activity in relation to BacLite by suspending BacLite product launches outside the US and EMEA. The halt of the US clinical ~~trials~~study in the fourth quarter of 2007 was followed by 3M further scaling back greatly its marketing, investment and related activity in relation to BacLite. 3M failed diligently to seek regulatory approval in Canada, or to market BacLite in Australia despite apparently having the import licenses necessary for marketing. Thus 3M failed to seek or obtain the necessary regulatory approvals, either diligently or at all, in any of the major markets beyond the approvals secured by Acolyte in the European Union prior to its sale to ~~3M~~ the First Defendant.

34. The First Defendant ~~3M~~ was thereby in breach of clause 4.14(b), if not other clauses, as a result of 3M ~~through~~ (a) failing to conduct the US ~~trials~~ clinical study properly in the first place and (b) compounding the problem by failing to appreciate promptly or at all how the ~~trials~~ clinical study could be improved or re-run and failing to take steps to rectify matters and thus advance regulatory approval and properly market BacLite.

Failure actively to market BacLite ~~actively~~

35. The First Defendant ~~3M~~ was in further breach of clause 4.14(a) in that 3M it failed to market BacLite (or indeed any of the other Earn Out Products) actively as the First Defendant ~~3M~~ undertook to do through 3M.

36. 3M has suggested as a reason for its lack of marketing that there was no significant demand for BacLite. In fact at all material times there was significant market interest in BacLite, and there would have been even more significant interest had there been proper marketing.

36A. In order to market BacLite actively, i.e. with the reasonable skill and care of a competent company experienced in the worldwide marketing of healthcare products including infection prevention and specifically MRSA detection products and with the aim of increasing the sales of BacLite in 2009, 3M was required to do the following:

(1) Make the product available to potential customers.

(2) Recruit appropriately qualified staff in sufficient numbers, in particular:

a. sales personnel, with technical microbiological expertise and with knowledge and experience of the needs and practices of hospital laboratories;

b. technical support staff with sufficient expertise to be trained in the BacLite product and then able to work closely with potential customers during product evaluations and satisfactorily address any technical questions or issues arising during such evaluations;

c. service support staff to deal with purchasing, invoicing and administration issues and field service engineers to set up, maintain and repair BacLite equipment used by customers.

(3) Train the sales, technical support staff, service support staff and field service engineers appropriately.

(4) Emphasise the benefits to potential customers of MRSA detection and the particular advantages of BacLite over competitor products.

(5) Identify accurately the class of customer likely to purchase BacLite following a successful evaluation, and to identify those within the potential customer who should be approached;

(6) Ensure that customers conducting evaluations fully understand the BacLite equipment and protocol before commencing their evaluation, monitor customer evaluations closely to ensure that protocol is followed and any problems are quickly addressed, and intensively follow up evaluations to increase the prospects of a sale;

(7) Produce sufficient numbers of BacLite kits to fulfil demand for pre-sale customer evaluations;

(8) Be prepared to commit significant investment in the early years of marketing in order to secure substantial long term future revenues, in particular, having regard to the "reagent rental" model adopted by 3M, whereby the BacLite equipment was paid for by the client through the cost of the reagents necessary to perform the tests. Such model necessarily entailed incurring substantial capital cost in the manufacture of the BacLite equipment, which would only be recouped in the long term through customer reagent orders and/or partially through lease finance arrangements.

(9) Providing potential customers with a sound business case for the use of the BacLite product.

36B. Following 3M's acquisition of Acolyte, 3M marketed BacLite within the UK and many other European countries from early 2007, around six weeks after the acquisition. BacLite was also marketed to some extent in the Middle East.

36C. In early 2007 and thereafter there was strong global demand for MRSA detection products, in particular a product such as BacLite which:

(1) had high sensitivity and specificity,

(2) had the ability to provide results within five hours,

(3) involved a semi-automated process,

(4) had the capacity for batch processing,

(5) was significantly cheaper than DNA sequence detection tests based upon the polymerase chain reaction ("PCR tests"),

(6) would only detect viable organisms (in contrast to PCR tests),

(7) would detect all new strains of MRSA (in contrast to PCR tests),

(8) would allow for a positive test to be rapidly followed up with the typing of MRSA strain (in contrast to PCR tests where a positive result would mean going back to the patient for a new sample) and,

(9) could be developed as a platform for further diagnostic tests.

37. ~~Pending disclosure the Claimants will rely on inter alia~~ Such demand was

38.

39. The Claimants will also rely on

among healthcare providers for rapid microbiological tests to assist patient care and disease control.

39A. There continued to be strong interest in MRSA screening tests with the features of BacLite in 2008. Although, by mid-2008, PCR-based DNA sequence detection tests such as BD GeneOhm were available, such tests were significantly more expensive than BacLite and required substantially greater skill to perform. Chromogenic tests had reduced their time to result to between 18 and 48 hours but remained much slower than BacLite and less able to be used in large batches.

39B. In particular, and without prejudice to the generality of the foregoing, in 2008 in the United States there was strong interest in MRSA screening tests from the US Department of Veteran Affairs (**"the VA"**). In 2007, the VA planned to implement nationwide screening at all VA facilities and sought to evaluate various MRSA screening tests including BacLite. The value of the VA contract was estimated by 3M variously as US $50 million and US $15 million. Such evaluations were initially to take place in late 2007, and were subsequently postponed to 2008 by the VA. BacLite's prospects for sales to the VA were dependent on first having obtained US regulatory approval.

40. As is apparent from the above BacLite's particular strength was in the significant market for products which produced a same day response but which were cheaper and better at detecting variants than the 1 hour response ~~genetic sequencing~~DNA sequence-based detection tests. [redacted]

40A. Despite the high levels of market interest in BacLite's MRSA screening test, 3M failed to convert such interest into substantial sales. In the United States and other Major Markets where regulatory approval was not obtained no such sales could be made as a result of the failure diligently to pursue regulatory approval. 3M was required to market in the Major Markets and in those other territories where regulatory approval had been obtained. In the Major Markets where regulatory approval for BacLite had been obtained or was not required, and those countries in the Middle East where regulatory approval had been

obtained, such failure was attributable wholly or substantially to 3M's failure actively to market BacLite. In particular:

(1) Overall, 3M's approach to the marketing of BacLite was naïve and not consistent with "active" marketing within the meaning of the Agreement in that 3M significantly underestimated:

a. the sophistication of the sales process for medical diagnostics products;

b. the number of staff required to launch a medical diagnostics product globally;

c. the amount of technical support required to be given to customers and the importance placed by customers on such support;

d. The importance of actively and closely monitoring customer evaluations to identify problems and ensure a successful outcome;

e. the length of time it would take to convert customer interest into sales;

f. the numbers of BacLite kits required for customer evaluations, especially where such evaluations were taking place at the same time as the US clinical study ; and

g. the amount of capital investment that would be required in launching a medical diagnostic product globally

(2) In the UK, 3M did not continue to use Bio-Sat as its distributor, despite Bio-Stat's substantial knowledge and experience of BacLite derived from its pre-sale marketing activities for Acolyte. Any new sales personnel recruited to replace Bio-Stat were bound to be deficient in such knowledge, and would have required time to learn and understand the UK market for BacLite, the BacLite product details and the marketing strategy for BacLite, in order to be able to actively market this product.

(3) Outside the UK, 3M generally used sales staff with insufficient knowledge and experience of either microbiology or hospital laboratory requirements and practices and/or the market for a product such as BacLite.

(4) 3M did not train its sales staff adequately. In particular, 3M has stated that sales staff were trained within a six week period after acquisition. Six weeks was an insufficient period for adequate recruiting and training to be completed.

(5) 3M did not employ enough technical support staff, field service engineers or service support staff in respect of BacLite . As a result, 3M was unable to offer sufficient technical assistance to customers conducting evaluations, who were consequently less likely to purchase BacLite.

(6) 3M made inappropriate use of the technical staff at Acolyte's Porton Down premises. Much of their time was spent assisting with the proposed transfer of manufacturing facilities to a new plant at Loughborough, planned for 2008; leaving them with insufficient time to assist in the evaluations and regulatory trials 3M was conducting in 2007 and 2008.

(7) 3M mis-targeted their approach to potential customers by focusing on infection control staff rather than microbiologists, the latter being the personel which would use BacLite if acquired, would understand BacLite, and would better appreciate its practical benefits to hospitals.

(8) 3M failed adequately to promote the benefits of BacLite, in particular: 3M failed to put forward any detailed financial analysis of the economic benefits to hospitals of adopting an MRSA detection programme. 3M failed sufficiently to emphasise the benefits of BacLite over PCR tests including but not limited to detecting a wider variety of MRSA strains; and 3M failed to promote BacLite as a platform for further diagnostic tests.

(9) Because of its naïve approach to marketing and also its shortages of staff and experience, 3M spent insufficient time assisting

customers in that 3M spent too little time setting up the BacLite evaluation and training the customer in how to use BacLite, and did not monitor customer evaluations intensively, thereby substantially reducing the prospect that an evaluation, even if successful, would result in a sale.

(10) 3M failed to produce enough BacLite kits to satisfy the demand from customers for evaluations. Severe BacLite kit shortages in late 2007 limited the global commercialisation of BacLite such that by 10 October 2007 at the latest all BacLite product launches outside Europe and the United States were put on hold. In particular, no product launch took place in Canada or Australia despite interest from potential customers there.

(11) 3M failed properly to identify the types of organisations likely to purchase BacLite as pleaded in paragraph 42 below.

41. As indicated above, 3M has cited the halted US clinical ~~trials~~study as a rationale for failing to progress any effective marketing. 3M appears to have failed to undertake marketing of any significant sort in any market except Europe, the Middle East and Africa ("EMEA") and thus failed to market actively in three of the four specified Major Markets. Even this marketing within the EMEA was not active within the meaning of clause 4.14(a). Clause 4.15 makes clear that although the First Defendant~~3M~~ did not undertake to perform all of its undertakings in the SPA in a manner that would increase payment to Vendors, the First Defendant ~~3M~~ did undertake to perform its undertakings in clause 4.14, including the undertaking in subclause 4.14(a), in a manner that increases payment to Vendors.

42. Further :

(1) Certain marketing activity was inappropriate; for example, targeting markets in the Netherlands where the use of throat swabs was compulsory and/or preferred whereas BacLite worked using nasal swabs.

(2) In the EMEA it appears that 3M targeted relatively small hospitals or health centres ~~were targeted~~whose turnover of samples was too low for the batch size of BacLite, whereas the primary market for

BacLite is in large hospitals with a large potential volume of samples or swabs in need of testing~~.~~ and are thus suited to the BacLite batch size.

42A. Further or alternatively, in making its decisions as to whether and to what extent BacLite would be marketed by 3M, 3M took into account factors which, by clauses 4.14 and 4.15, the First Defendant had undertaken would not affect the active marketing of BacLite. In particular, 3M decided to stop marketing BacLite because (in part) of the monthly losses which it was incurring as a result of the costs of developing and marketing BacLite. As pleaded in paragraph 6B(3) above, the obligation actively to market was not qualified by reference to the current or forecast profitability of the product nor by the actual versus forecasted sales of the product.

42B. ~~Pending disclosure and/or further information, the~~The First Defendant relies in particular on letters from 3M dated 14 July 2008 and 31 October 2008, in both of which 3M cited the monthly losses allegedly incurred by 3M in respect of Acolyte (put variously at USD500k and USD800k) as one of the reasons for 3M seeking the First Defendant's consent to the cessation of the business of development and marketing of the Earn Out Products. It is to be inferred that such alleged losses were a substantial factor in 3M's earlier decision ~~no later than about April 2008~~ to cease ~~active~~ marketing of the Earn Out Products, including BacLite, outside the EMEA, following the decision not to re-run the US clinical study.

42C. Further or alternatively, 3M did not actively market BacLite in that it did not devote similar resource, expenditure, effort and expertise or accord similar priority to the marketing of BacLite as to the marketing of other products within 3M's Medical Division. The Claimants rely on the facts and matters pleaded in paragraphs 44 to 48 below, which also amount to breaches of the general obligation actively to market BacLite contained in clause 4.14(a).

43. Overall 3M appeared to "give up on" BacLite in about April 2008 at the latest ~~in the sense of abandoning any serious efforts to market it~~ outside the EMEA, and within the EMEA continuing to fail to market BacLite and the other Earn Out Products actively within the meaning of the SPA, despite the fact that under the SPA the First Defendant ~~it~~ was obliged to comply with clause 4.14

through 31 December 2009 in a manner that would increase the Earn Out Payment due to Vendors in early 2010.

Failure to support the business of selling Earn Out Products

44. In breach of SPA clause 4.14 (c) the First Defendant failed to support the business selling the Earn Out Products with resources to a similar overall degree as made available to other businesses within 3M's Medical Division.

[redacted]

45. [redacted]

~~**Inadequate training that undermined BacLite from the outset**~~

~~46. 3M's sales personnel lacked from the outset the background or training necessary to succeed, and were invited by 3M to think of BacLite as a technology about to the replaced thus undermining BacLite among those who should have been expected to promote it to customers.~~

~~47. Pending disclosure the Claimants will contend that the standard of the training materials and processes for BacLite of which they are aware of to date served only to undermine BacLite and announce its replacement.~~ [redacted] ~~The marketing that was undertaken utilised personnel who were insufficiently qualified and/or trained and marketing materials that were inappropriate.~~

~~Marketing and other training and customer support materials~~

48. ~~The Claimants repeat the above paragraphs. Further 3M failed to employ or utilise in its sales and marketing teams persons of sufficient calibre to perform effectively, and/or failed to provided sufficient or appropriate training for the sales force.~~

Cessation by 3M of the business in relation to BacLite and the Earn Out Products generally

49. By a letter of 15 August 2008, 3M demanded the consent of the vendors pursuant to clause 4.14(i)(i) to cease business in relation to the Earn Out Products, under penalty of forgoing any Earn Out Payment if they did not so consent by 28 August 2008. By a further letter dated 31 October 2008 3M asserted that:

(1) Continuation of the business in relation to the Earn Out Products had no commercial justification, with monthly losses to 3M at $800,000, likely to total $9,600,000 by the end of 2009;

(2) A failure to consent to cessation of the business would be a breach by the Vendors of clause 4.14(i)(i), as to which 3M reserved their rights (i.e. to sue for damages for breach of clause 4.14(i)(i));

(3) the Vendors should consent to cessation of the business and rely on their rights to claim damages for breach of the SPA.

50. By their breaches of the SPA as set out above and/or by their further conduct in sending the letter of 15 August 2008 as set out above, the First Defendant through 3M repudiated the SPA. By a letter from their lawyers dated 12 November 2008, three Vendors including the First Claimant informed 3M (and thereby informed the First Defendant) of their position that the First Defendant~~3M~~ had already ceased to perform and repudiated the SPA, and that these Vendors reserved their rights to damages, and accepted the repudiation of the SPA subject to damages.

51. ~~Although 3M had in fact ceased to market BacLite in any meaningful sense by April 2008 at the latest it sought to create the impression that it had continued to do so by announcing in early December that it would cease development and sales of it by 31 December 2008, stating that BacLite "does~~

~~not meet customer needs across Europe as well as expected~~" By reason of 3M's cessation of the business, the First Defendant breached clause 4.14(i)(i) of the Agreement because the Claimants had not consented to such cessation, nor (insofar as material) had the Claimants' consent been unreasonably withheld, as pleaded in paragraph 39C of their Re-Amended Reply and Defence to Counterclaim).

D. DAMAGES AGAINST THE FIRST DEFENDANT

52. By reason of the matters set out above, the Claimants have suffered loss and damage. Had 3M performed as the First Defendant ~~it~~ undertook it would ~~to~~ do, the business in relation to the Earn Out Products would have continued throughout 2008 and 2009, and Earn Out Product Net Sales through 2009 payable in 2010 would have been at least ~~£41~~ 40 million. In fact Earn Out Product Net Sales in 2009 will be ~~zero~~ minimal as a result of 3M's decision not to take the steps which the First Defendant promised 3M would take under the SPA ~~perform~~. By this method the loss and damage suffered by the Claimants is their pro rata share, in accordance with column (4) of Schedule 1 of the SPA, of the Net Sales which would have been achieved (less any credit for the total amount of Employee Incentive Payments which would have been made). In particular:

(1) In the EMEA territory, 3M would have marketed BacLite more extensively in those countries in the Middle East where regulatory approval had been obtained and would have marketed throughout Europe and not only in the UK and other countries in Western Europe.

(2) In the United States, 3M would have obtained regulatory approval by the end of 2007 on the basis of sensitivity and specificity similar to that observed in BacLite's UK trials. 3M would have commenced marketing in the United States at the beginning of 2008.

(3) 3M would have obtained the relevant regulatory approvals for Canada by the end of 2007 and marketing would have commenced in around the beginning of 2008.

(4) BacLite did not require regulatory approval in Australia, only an importation license and an ISO 13485:2003 certification, and marketing therefore should have commenced in Australia from mid-2008.

(5) Such marketing, as described in sub-paragraphs (1) to (4) above would have resulted in sales revenue of at least £40 million in 2009.

(6) Alternatively, if (contrary to the Claimants' primary case) the original US clinical studies would have failed to achieve the required sensitivity or selectivity even if diligently pursued, 3M should, acting diligently, have re-run the US clinical studies by mid-2008, which trials if diligently performed would or would likely have shown sensitivity and specificity similar to that observed in the UK trials. Marketing in the United States would then have commenced in around mid-2008. The commencement of marketing in Australia and Canada would have been unaffected.

(7) On the above alternative basis, such marketing would have resulted in sales revenue of at least £32 Million in 2009.

52A. In the alternative to the damages claim pleaded in paragraph 52 above in respect of revenues in the United States the Claimants claim damages on a loss of a chance basis, to reflect the chance that if 3M UK had performed its obligations under clause 4.14 of the SPA US regulatory approval would or would likely have been obtained at the end of 2007, alternatively some later date, and that substantial sales revenues for BacLite in those territories, as aforesaid in paragraph 52, would have been achieved in 2009.

52B. In the further alternative, the Claimants claim damages in the amount which a reasonable person in the position of 3M UK would have been prepared to pay to the Claimants to secure their consent to 3M cease to carry on the development or marketing of the Earn Out Products.

53. For the avoidance of doubt, the Claimants do not admit that any cap on damages under clause 10.1 of the SPA would be applicable, and refer to those matters plead in paragraph 37 of the Amended Reply and Defence to Counterclaim. ~~Whilst the Claimants currently advance no positive case herein that the conduct of 3M was fraudulent, pending further investigation of such~~

~~conduct, they reserve the right to apply to do so if so advised on completion of such investigation and/or after disclosure and/or Further Information from 3M.~~

E. INDUCEMENT OF BREACH OF CONTRACT

54. The Second Defendant procured that the First Defendant ceased from around October 2007 outside the United States and the EMEA, and from April 2008 at the latest in the United States, actively to market BacLite and/or ceased from around April 2008 at the latest diligently to pursue regulatory approvals (insofar as it had ever done so) in respect of BacLite. The Second Defendant did so in the knowledge that the First Defendant was thereby breaching its obligations under clause 4.14 and 4.15 of the SPA.

55. The Second Defendant is the ultimate parent company of the First Defendant. At all material times, the Second Defendant knew of the existence and terms of the SPA, in particular of the acts which the First Defendant undertook 3M would perform in clauses 4.14 and 4.15 of the SPA. ~~Pending disclosure and/or provision of further information, the~~The Claimants rely, in particular, on the following facts and matters as evidencing the Second Defendant's knowledge:

(1) The negotiations for the SPA, which took place between August 2006 and February 2007 at first proceeded on the basis that the Second Defendant would be the Purchaser. Only from around December 2006 did the structure of the proposed agreement change such that the First Defendant became the intended Purchaser.

(2) Both during the initial period of negotiations when the Second Defendant was the intended Purchaser and thereafter, the negotiations were conducted for the intended Purchaser by employees of the Second Defendant or of companies within the 3M Group other than the First Defendant, namely: Charles Kummeth, Angela Dillow, Mark Schroer, Jordan Fineberg, Henry Chang, Finn Haley, Louis Lambert, James Zappa, Nancy Lambert. The Second Defendant had knowledge of the SPA and its terms through the aforementioned persons. Only one member of 3M's team involved

In the negotiations of the SPA, Mr. Whitworth, was an employee of the First Defendant.

(3) The SPA was signed for and on behalf of the First Defendant by Mr. Charles Kummeth who was, at the time, Division Vice President of 3M Medical Division, being a business group of the Second Defendant. Accordingly, the Second Defendant had knowledge of the existence and terms of the SPA through Mr. Kummeth.

(4) As set out below, the obligations of the First Defendant under clauses 4.14 and 4.15 of the SPA were to be performed through 3M. It is to be inferred that the Second Defendant was aware of the nature of the obligations which the First Defendant had undertaken that the group of which it was parent would perform.

(5) Further, the correspondence with the Vendors' representative in mid to late 2008 by which 3M proposed that the business of developing and marketing the Earn-Out Products should cease was conducted by representatives of the Second Defendant, namely Mr. Kummeth, Mr. Ingebrand (Global Business Director, Infection Prevention), and Maureen Harms (Assistant General Counsel, 3M Legal Affairs). Such correspondence revealed the Second Defendant's knowledge (through the above named persons) of the terms of the SPA including clauses 4.14 and 4.15.

(6) [redacted]

56. As pleaded in paragraph 6A above, the First Defendant undertook that the steps required by clauses 4.14 and 4.15 would be taken by 3M, i.e. by the

First Defendant, the Second Defendant and companies within the 3M Group as a whole.

57. The marketing of the Earn-Out Products (including BacLite) and the development of the Earn-Out Products, including the pursuit of regulatory approvals outside Europe in respect of BacLite, was directed and controlled by the Second Defendant, as the ultimate parent company of the 3M Group. In particular, and without prejudice to the generality of the foregoing, the control exercised by the Second Defendant over the performance of obligations under clause 4.14 and 4.15 is evidenced by the following:

(1) The statement of Ms. Harms of 3M Legal Affairs in her letter of 31 October 2008 that:

"On 13 February 2007, 3M UK entered into the Agreement to acquire Acolyte from your clients, the "Vendors" as defined in the Agreement. Since that time 3M UK, through the wider 3M group of companies (together referred to as 3M), has worked in good faith with its obligations under the Agreement"

(2) The statements in Ms. Harms' letter of 31 October 2008 to the effect that the decisions made as to the extent of marketing and development of the Earn-Out Products and as to the cessation of such activities were made by the 3M Group as a whole and were based on the interests of the 3M Group as a whole.

(3) The description in Ms. Harms' letter dated 31 October 2008 of the obligations under clause 4.14(a) and (b) as being "3M's obligations" notwithstanding that only the First Defendant had undertaken contractually that they would be performed. Such description was an acknowledgment that it was 3M who would be performing the obligations in clause 4.14(a) and (b) and that it would be for the controlling entity of 3M, namely the Second Defendant, to procure (or not procure, as the case may be) performance of the First Defendant's obligations.

(4) It was the Second Defendant rather than the First Defendant that demanded by letter dated 15 August 2008 that the Claimants consent to the cessation of the business of the development and

marketing of the Earn-Out Products. It is to be inferred that such request was the result of or was influenced by the fact that in or before June 2008 the Second Defendant had acquired a substantial one-time gain, against which it wished, during 2008, to utilise losses incurred in relation to the Acolyte business for the Second Defendant's benefit. It is to be inferred that the Second Defendant was able to exercise control over the First Defendant in respect of the performance of its obligations by making the abovementioned request, thereby seeking to utilise Acolyte losses against its one-time gain.

58. By April 2008 at the latest, wrongly and in breach of clause 4.14(b), all efforts to obtain approvals outside EMEA ceased. Such cessation was procured by the Second Defendant with knowledge that in doing so the First Defendant was being placed in breach of the SPA:

(1) On 26 November 2007 the US trials of BacLite were put "on hold" as a result of the worse results in those trials than had been achieved in the UK trials. After November 2007, as a result of the problems with the US trials, efforts to obtain regulatory approval in Australia were also put on hold. Subsequently, in March 2008 efforts to obtain regulatory approval in Canada were put on hold, again because of the problems with the US trials. The US trials were not subsequently restarted and no further attempts were made to obtain regulatory approval in Canada or Australia.

(2) The attempts to obtain regulatory approval in the USA, Canada and Australia were made by the 3M Medical Division and were directed and controlled by the Second Defendant.

(3) [redacted]

[redacted]

(4) In the premises, by January 2008 at the latest, the Second Defendant knew that, in breach of clause 4.14(b), regulatory approval for the USA had not been diligently sought in late 2007. The Second Defendant knew that unless the US trials were promptly re-run using an appropriate comparator (i.e. MSAOx) and with incubator temperatures consistently set and maintained at the correct level amongst other requirements there would be further breaches of clause 4.14(b) because of an ongoing lack of diligence with regard to seeking regulatory approval in the USA.

(5) However, by April 2008 at the latest, the Second Defendant had decided not to pursue any clinical testing of BacLite in the USA and had thus abandoned any attempt to obtain regulatory approval for BacLite in the USA.

(6) In acting as aforesaid, the Second Defendant procured the breach by the First Defendant of clause 4.14(b) as a result of the failure from April 2008 at the latest diligently to rerun the US trials and/or the cessation of marketing of BacLite, and the Second Defendant did so with knowledge that such breach would occur.

59. ~~In or around April 2008, wronglyw~~Wrongly and in breach of clause 4.14(a) of the SPA, BacLite ceased to be marketed ~~actively~~ in any substantial way or at all, from October 2007 outside the United States and EMEA, and from April 2008 at the latest within the United States. Such cessation was procured by the Second Defendant with knowledge that in doing so the First Defendant was being placed in breach of the SPA:

~~(1) As a result of the abandonment, no later than April 2008, of efforts to obtain regulatory approvals for BacLite outside EMEA, no marketing of BacLite in regions outside EMEA took place in or after April 2008. Accordingly, by procuring breach by the First Defendant of its obligations under clause 4.14(b), the Second Defendant also procured breach by the First Defendant of its obligations actively to market BacLite outside EMEA.~~

~~(2) From April 2008 at the latest, no serious efforts were made to market BacLite within EMEA, including within the European Union. In the premises, from April 2008 at the latest, BacLite was not actively marketed in EMEA within the meaning of the SPA.~~

(3) As pleaded in paragraph 57 above, the Second Defendant directed and controlled the marketing of BacLite. Further, the Second Defendant knew that the First Defendant could not unilaterally decide to stop active marketing of BacLite. In the premises, the Second Defendant procured the cessation of ~~active~~ all or any substantial marketing of BacLite in territories outside EMEA as aforesaid ~~within EMEA from at least April 2008~~, knowing that by doing so it was placing the First Defendant in breach of the SPA.

60. The Claimants have suffered loss and damage as a result of the Second Defendant's wrongful inducement of the First Defendant's breach of the SPA. If the Second Defendant had not committed such a tort, the US trials would have been re-run no later than April 2008, Canadian ~~and Australian~~ regulatory approvals and Australian import licences would have been obtained and, after obtaining the necessary approvals, BacLite would have been actively marketed in the USA, Canada and Australia. ~~Furthermore the securing of regulatory approval in the United States would have been a persuasive factor in securing entry into the markets of other territories (including the Far East and South America) enabling BacLite to be marketed in these territories.~~ Also, BacLite would have been actively marketed in EMEA in the period April 2008 to date. Had such development and marketing taken place, substantial sales revenue of BacLite would have been generated in the calendar year ending 31 December 2009, amounting to at least £32 Million ~~£41 million~~. Accordingly, the Claimants claim damages from the Second Defendant in the amount of their pro rata share (in accordance with column (4) of Schedule 1 of the SPA) of such amount (less any credit for the total amount of Employee Incentive Payments which would have been made).

AND the Claimants claim as against the First Defendant:

(1) Damages for breach of contract

(2) Interest to be assessed pursuant to s.35A of the Supreme Court Act 1981;

(3) Costs;

(4) Such other relief as the Court may think fit

AND the Claimants claim as against the Second Defendant:

(1) Damages in tort for inducement of breach of contract;

(2) Interest to be assessed pursuant to s.35A of the Supreme Court Act 1981;

(3) Costs;

(4) Such other relief as the Court may think fit.

RICHARD LORD Q.C.

JEFFERY ONIONS Q.C.

SA'AD HOSSAIN

STATEMENT OF TRUTH

The Claimants believe that the facts stated in these Re-Amended Particulars of Claim are true.

I am duly authorised by the Claimants to sign this statement.

Gary Moss, Partner of McDermott Will & Emery UK LLP

Signed .....

Re-Served this 28 day of July 2010 by McDermott Will & Emery UK LLP, solicitors for the Claimants, of 7 Bishopsgate, London EC2N 3AR.